15 CV 00362

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BIOMARIN PHARMACEUTICAL INC. Plaintiff, v. DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC. Defendants.	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff BioMarin Pharmaceutical Inc. ("BioMarin") for its complaint against Dr. Reddy's Laboratories Ltd. and. Dr. Reddy's Laboratories Inc. (collectively "Dr. Reddy's") hereby alleges as follows:

NATURE OF ACTION

1. This action involves the fundamental right of a company to decide whether and with whom it will do business. Dr. Reddy's is seeking to require BioMarin to sell samples of its proprietary and patented branded drug Kuvan® (sapropterin dihydrochloride) to Dr. Reddy's for use in bioequivalence studies that Dr. Reddy's wishes to use in support of its efforts to secure Food and Drug Administration ("FDA") approval of an Abbreviated New Drug Application ("ANDA") for a generic form of Kuvan®. BioMarin does not wish to sell product to Dr. Reddy's, its market competitor, and has thus refused the demand of Dr. Reddy's. In response,

Dr. Reddy's has threatened BioMarin with legal action. In order to resolve this dispute, BioMarin brings this case under 28 U.S.C. §§ 2201 and 2202 seeking a declaration of its rights.

2. In December 2007, BioMarin obtained FDA approval for Kuvan®, the first and only FDA-approved drug to treat patients with hyperphenylalaninemia ("HPA") due to tetrahydrobiopterin ("BH4-") responsive Phenylketonuria ("PKU").

3. BioMarin distributes Kuvan® through specialty mail-order pharmacies, meaning Kuvan® is not available through drug wholesalers.

4. Unable to obtain Kuvan® through drug wholesalers or specialty pharmacies, Dr. Reddy's contacted BioMarin by letters dated January 17, 2013, May 12, 2014, and May 16, 2014, seeking to obtain Kuvan® tablets from BioMarin directly. In the May 12, 2014 letter, Dr. Reddy's accused BioMarin of "anticompetitive" behavior in violation of the antitrust laws and threatened to contact the Federal Trade Commission ("FTC") if BioMarin did not accede to its demands.

5. It is well settled that the antitrust laws do not impose a duty to deal with rivals absent limited circumstances not present here. BioMarin therefore seeks a judgment by this Court declaring that BioMarin has no duty to sell Kuvan® to Dr. Reddy's.

PARTIES

6. BioMarin is a California pharmaceutical company incorporated in 1997 with its principal place of business at 105 Digital Drive, Novato, California 94949. BioMarin focuses on developing drugs for the treatment of chronic and degenerative genetic conditions that lack effective therapies and affect relatively small numbers of patients, many of whom are children. Since its founding in 1997, BioMarin has developed and commercialized five products, four of which are sold in the United States.

7. Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") is an Indian company with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India. Upon information and belief, Dr. Reddy's Ltd. is in the business of, among other things, making and selling generic pharmaceutical products, which it distributes throughout the United States, including in this judicial district, through at least Dr. Reddy's Laboratories Inc.

8. Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") is a New Jersey corporation with its principal place of business at 107 College Road East, Princeton, New Jersey 08540. Upon information and belief, Dr. Reddy's Inc. is in the business of, among other things, marketing and selling generic versions of branded pharmaceutical products, which it distributes throughout the United States, including in this judicial district.

9. Dr. Reddy's Inc. is a wholly owned subsidiary of Dr. Reddy's Ltd. and is controlled by Dr. Reddy's Ltd. Upon information and belief, Dr. Reddy's Inc. is primarily engaged in the marketing of Dr. Reddy's Ltd.'s products in the United States, including in this judicial district. Upon information and belief, the majority of the products Dr. Reddy's Inc. sells in the United States, including in this judicial district, are manufactured in India by Dr. Reddy's Ltd. pursuant to ANDAs filed with the FDA by Dr. Reddy's Ltd.

10. Upon information and belief, Dr. Reddy's Inc. is Dr. Reddy's Ltd.'s exclusive agent in the United States.

JURISDICTION AND VENUE

11. This case is being brought under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, and raises issues under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

12. This Court has personal jurisdiction over Dr. Reddy's Ltd. and Dr. Reddy's Inc. pursuant to 15 U.S.C. § 22. This Court also has personal jurisdiction over Dr. Reddy's by virtue of, *inter alia*, the following facts:

- Dr. Reddy's Inc. (and through it, Dr. Reddy's Ltd.) has a presence in New York;
- Dr. Reddy's Inc. and Dr. Reddy's Ltd. have availed themselves of the rights and benefits of New York law by filing at least one case in this judicial district. *See Dr. Reddy's Labs. Inc. & Dr. Reddy's Labs. Ltd. v. Aaipharma, Inc.*, 1:01-cv-10102 (S.D.N.Y. Nov. 14, 2001);
- Dr. Reddy's Inc. and/or Dr. Reddy's Ltd. have previously stipulated and/or consented to personal jurisdiction in the Federal District Courts of New York on at least 16 other occasions within the past 14 years;
- both Dr. Reddy's Inc. and Dr. Reddy's Ltd. admitted that they are "subject to personal jurisdiction within this judicial district" in at least the following cases: *Astrazeneca AB v. Dr. Reddy's Labs., Ltd.*, Docket No. 1:07-cv-06790 (S.D.N.Y. July 27, 2007); *In re Rivastigmine Patent Litig.*, Docket No. 1:05-md-01661 (S.D.N.Y. Feb. 18, 2005); *Novartis Corp. v. Dr. Reddy's Labs. Ltd.*, No. 1:04-cv-06045 (S.D.N.Y. Aug. 4, 2004);
- Dr. Reddy's Inc. (and through it, Dr. Reddy's Ltd.) conducts business in New York and has availed itself of the rights and privileges of doing business in New York by continuously and systematically placing goods in the stream of commerce for distribution throughout the United States, including this judicial district, and/or by selling, directly or through its agents, pharmaceutical products in this judicial district; and

- upon information and belief, Dr. Reddy's Ltd. also transacts business in this judicial district through its wholly owned subsidiary Dr. Reddy's Laboratories New York, Inc., which is licensed to do business in the state of New York.

13. Venue is appropriate in this district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391.

FACTUAL BACKGROUND

14. On December 13, 2007, BioMarin obtained FDA approval of its New Drug Application ("NDA") to market Kuvan® (sapropterin dihydrochloride) to treat patients with hyperphenylalaninemia ("HPA") due to tetrahydrobiopterin ("BH4-") responsive Phenylketonuria ("PKU"). Kuvan® is the first and only FDA-approved medication to reduce blood phenylalanine, or Phe, levels in patients with HPA due to BH4- responsive PKU.

15. PKU is a genetic disorder characterized by the absence or deficiency of an enzyme responsible for processing the essential amino acid phenylalanine, which is present in a wide variety of foods and beverages. If untreated, persons with PKU quickly build up toxic levels of Phe in their bloodstreams, which can lead to moderate to severe cognitive impairment, developmental disabilities, seizures, and other serious medical conditions.

16. BioMarin's Patient and Physician Support ("BPPS") group reviews and approves all prescriptions for Kuvan®. BPPS assists patients in obtaining coverage from their insurance companies. BPPS also helps patients who do not have insurance, or who have insurance but cannot afford their co-payments, obtain Kuvan®. Additionally, the BPPS group helps patients remain compliant with their Kuvan® regimen by continuing to interface with the patients' insurance companies, which often require annual recertification, and by contacting new

insurance companies to obtain authorization for Kuvan® when a patient's insurance company changes, such as when a patient or a patient's parent changes jobs.

17. Kuvan® is distributed through specialty pharmacies. Kuvan® is not distributed through drug wholesalers.

18. By letter dated January 17, 2013, Dr. Reddy's requested that BioMarin sell it 14 bottles of 120 tablets each of Kuvan® for use in conducting bioequivalence testing.

19. As is its right, BioMarin did not respond to the January 17, 2013 letter.

20. Dr. Reddy's interpreted BioMarin's silence as an indication that BioMarin was unwilling to sell samples of Kuvan® to Dr. Reddy's, and thus sent another letter dated May 12, 2014, requesting that BioMarin sell 2,000 tablets of Kuvan® to Dr. Reddy's. In the letter, Dr. Reddy's asserted that BioMarin's refusal to sell is "improper under the antitrust laws." Further, Dr. Reddy's asserted that BioMarin's refusal raises "anticompetitive concerns" that would likely be "troubling" to the FTC. Dr. Reddy's threatened to report BioMarin to the FTC, stating that Dr. Reddy's has "held off contacting the FTC for now, in the hope that you will reconsider your position."

21. On May 16, 2014, Dr. Reddy's sent another letter to BioMarin to include the attachments to the May 12, 2014 letter, which were inadvertently omitted.

22. By letter dated October 3, 2014, Dr. Reddy's informed BioMarin that it had filed an ANDA with the FDA seeking approval to market a generic version of Kuvan®.

23. Applications to market generic drugs are deemed "abbreviated" because they generally are not required to include preclinical or clinical studies demonstrating safety and effectiveness. Rather, ANDAs rely on the safety and effectiveness demonstrated by the innovator of the branded version of the drug. To rely on the innovator's clinical trials, the

ANDA must include information showing that the proposed new drug is bioequivalent to a previously approved listed drug (that is, that the generic drug is absorbed to substantially the same extent and at substantially the same rate in the human body as the branded drug). 21 U.S.C. § 355(j)(2)(A)(iv); 21 C.F.R. § 320.1(e).

24. On information and belief, the ANDA Dr. Reddy's filed with the FDA does not include information showing its generic version of Kuvan® is bioequivalent to the FDA-approved version of Kuvan®.

BIOMARIN HAS NO LEGAL OBLIGATION TO DEAL WITH COMPETITORS

25. BioMarin is under no legal duty to sell or otherwise supply samples of Kuvan® to Dr. Reddy's. The Supreme Court has held that a company has the fundamental right to choose with whom it deals. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004); *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919).

26. As the Second Circuit has repeatedly held, the only exception to the freedom a company has to choose with whom it will deal may arise where the company terminates a prior, voluntary course of dealing with its rivals. *E.g.*, *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134 (2d Cir. 2014); *In re Elevator Antitrust Litig.*, 502 F.3d 47, 52-53 (2d Cir. 2007). Here there is no such voluntary, prior course of dealing, and thus BioMarin has no legal obligation to sell or provide Kuvan® to Dr. Reddy's.

COUNT I
(Declaratory Relief)

27. BioMarin incorporates by reference paragraphs 1-26 as if set forth fully herein.

28. Dr. Reddy's has demanded from BioMarin samples of BioMarin's patent-protected drug Kuvan® so that Dr. Reddy's can conduct bioequivalence testing in support of its ANDA seeking FDA approval for a generic form of Kuvan®.

29. BioMarin has exercised its legal right to refuse to deal with Dr. Reddy's. Dr. Reddy's has accused BioMarin of engaging in anticompetitive conduct that is improper under the antitrust laws and has threatened to involve the FTC.

30. Accordingly, there is currently an actual controversy between BioMarin and Dr. Reddy's regarding BioMarin's legal right to decline to sell Kuvan® samples to Dr. Reddy's.

31. Pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, BioMarin is entitled to a declaration of rights whereby it is declared that BioMarin has no duty or obligation to provide Kuvan® samples to Dr. Reddy's.

PRAYER FOR RELIEF

WHEREFORE, BioMarin respectfully requests judgment in its favor and against Dr. Reddy's as follows:

a) declaring that BioMarin is under no legal obligation to sell or otherwise provide samples of Kuvan® to Dr. Reddy's; and

b) awarding such other relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury of this action.

January 16, 2015

Respectfully submitted,

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